K020078

FEB 27 2004

510(k) Summary of Safety and Effectiveness

This 510(k) Summary for Exactech Resorbable Bone Paste is provided as required per Section 513(1)(3) of the Food, Drug and Cosmetic Act.

1. Submitter:

Exactech Inc.
2320 NW 66th Court
Gainesville, Florida 32653
Telephone 352-377-1140
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Contact person:

Steve Lin, D.Sc
Vice President, Advanced Technology & Business Development
Exactech Inc.
Telephone 352-377-1140
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Date of original submission: 01-08-2001

FDA Establishment Number 1038671

2. Proprietary Name: Exactech Resorbable Bone Paste
Common Name: Bone void filler
Product Code: MQV
Device Class: Not classified
Classification Panel: Orthopaedic

3. Legally Marketed Devices for Substantial Equivalence Comparison:

Product Code	Manufacturer	510(k) Number	Product
MQV	Wright	K963562	Wright Plaster of Paris Pellets
MQV	EBI	K011386	EBI Osteostim Granules – Resorbable Bone Graft Substitute
MQV	Neu Coll Laboratories	K000122	Collagraft Strip Bone Graft Matrix

4. Comparison to the Predicate Device(s):

Exactech Resorbable Bone Paste shares the same function and intended use and therefore is substantially equivalent to Wright Medical – Plaster of Paris (Osteoset), Neu Coll Laboratories – Collagraft Strip and EBI – EBI OsteoStim Granules – Resorbable Bone Graft Substitute as a bone void filler.

The polymer carrier used in Exactech Resorbable Bone Paste absorbs in-vivo and is used solely for the ease of handling and delivery of DBM.

5. Device Description:

Exactech Resorbable Bone Paste is a mixture of demineralized bone matrix (DBM) in a bioinert polyethylene glycol (PEG) based polymer and is provided as an aseptic manufacture single use, ready to use implantable device derived from a single donor. DBM resorbs and is replaced with new bone during the healing process.

6. Indications for Use

Exactech Resorbable Bone Paste is intended for use as a bone graft extender (extremities, spine, pelvis) and as a bone void filler for bony voids or gaps of the extremities and pelvis that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Exactech Resorbable Bone Paste may be used with rigid fixation systems.

7. Contraindications:

Exactech Resorbable Bone Paste is not intended to provide structural support during the healing process; therefore, Exactech Resorbable Bone Paste is contraindicated in cases where structural support of the skeletal system is required by the graft during healing.

This allograft should not be implanted into sites with an active infection.

Polymixin Sulfate B and Bacytracin are used in processing this graft and trace amounts remain. Since it is impossible to quantify the levels at which any individual may have an allergic response, this product is contraindicated in patients with known sensitivity.

8. Safety and Effectiveness Information:

Human demineralized bone used in Exactech Resorbable Bone Paste is single-donor processed, biocompatible, safe and effective for the repair of bone defects. Exactech Resorbable Bone Paste is aseptic manufactured for single patient use.

The polymer carrier used in Exactech Resorbable Bone Paste is bioinert and biocompatible with host tissue and presents no new safety issues.

The biocompatibility and efficacy of aseptically manufactured demineralized bone matrix has been established through its long history of safe and effective use as a human tissue for transplant without reported incidents of infection or complication. A viral reduction study was conducted by a CLIA certified testing laboratory using four virus models representing RNA, DNA,

envelope and non-envelope virus, which included: 1) *Hepatitis A Virus (HAV)*, non-enveloped, RNA-containing picornavirus 2) *Human immunodeficiency virus type 1* (HIV-1) enveloped, RNA-containing retrovirus, 3) *Porcine parvovirus (PPV)* non-enveloped, DNA-containing parvovirus, which serves as a model for other parvovirus such as human parvovirus B19 and 4) *Pseudorabies virus (PrV)*, enveloped, DNA-containing virus belonging to the Herpesviridae family and serves as a model for other herpesviruses such as Cytomegalovirus (CMV). This study demonstrates the demineralization process used on donor bone contained in Exactech Resorbable Bone Paste effectively eliminates or reduces the virus responsible for potential infectious disease, which include HIV and Hepatitis.

9. Non-Clinical Testing:

Each lot of DBM is screened for osteoinductivity potential, with only acceptable DBM being manufactured into Exactech Resorbable Bone Paste. Osteoinductivity of each lot of Exactech Resorbable Bone Paste is verified using a single test protocol and demonstrates the DBM and the product to be osteoinductive in the athymic mouse. Osteoinduction assay results in the athymic mouse model should not be interpreted to predict clinical performance in human subjects.

Test samples are implanted bilaterally into the gastrocnemius muscle of 2 animals (total of 4 samples of each lot), explanted at day 35 and scored for osteoinductivity in accordance with the test protocols defined by Schwartz S. Mellonig, JI, Carnes, Jr. DL, de la Fontaine J, Cochran DL, Dean DD, Boyan BD (1996) *Ability of Commercial Demineralized Freeze-dried Bone Allograft to Induce New Bone Formation* J. Perio 67:918-926 and the ASTM Draft Standard *Guide for the Assessment of Bone Inductive Material.* A score of 1-4 is assigned with:

1 = implant present no new bone or cartilage present
2 = endochondral ossification <25% implant site and/or new bone covering <25% of implant
3 = endochondral ossification 26-50% implant site and/or new bone covering 26-50% of implant
4 = >50% endochondral ossification and/or new bone covering > 50% of implant

A viral reduction study was conducted by a CLIA certified testing laboratory using four virus models representing RNA, DNA, envelope and non-envelope virus, which included: 1) *Hepatitis A Virus (HAV)*, non-enveloped, RNA-containing picornavirus 2) *Human immunodeficiency virus type 1* (HIV-1) enveloped, RNA-containing retrovirus, 3) *Porcine parvovirus (PPV)* non-enveloped, DNA-containing parvovirus, which serves as a model for other parvovirus such as human parvovirus B19 and 4) *Pseudorabies virus (PrV)*, enveloped, DNA-containing virus belonging to the Herpesviridae family and serves as a model for other herpesviruses such as Cytomegalovirus (CMV). This study demonstrates the demineralization process used on donor bone contained in Exactech Resorbable Bone Paste significantly diminishes these model viruses and can reasonably be anticipated to diminish the titers of other viruses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2004

Ms. Rebecca S. Roberts CTBS
Sr. Regulatory Representative
Tissue Bank Director
Exactech
2320 NW 66th Court
Gainesville, Florida 32653

Re: K020078
Trade Name: Exactech Resorbable Bone Paste
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: November 25, 2003
Received: December 1, 2003

Dear Ms. Roberts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D, M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech Resorbable Bone Paste

Indications for Use

510(k) Number (if known): K020078

Device Name: Exactech Resorbable Bone Paste

Indications for Use:

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Exactech Resorbable Bone Paste may be used with rigid fixation systems.

Prescription Use _X_. (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K020078